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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,981	11/18/2003	Lars Andersson	4448-3	3661
23117	7590	12/23/2004		
NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714			EXAMINER ISABELLA, DAVID J	
			ART UNIT 3738	PAPER NUMBER

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/714,981

Applicant(s)

ANDERSSON ET AL.

Examiner

DAVID J ISABELLA

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 1-29 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1,4-12,14-24,27,28 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Shifrin et al (5476471).**

Shifrin et al discloses a device for correction of vascular junctions. Shifrin, et al uses fibers 11 embedded in the biocompatible coating. The fibers are shown as being spaced apart and extending in a direction along the axis of the device as broadly claimed. The fibers are metallic and are therefore radiopaque and thus meets the limitations of the claims.

Claim 4, see column 3, lines 14+ of Shifrin et al.

Claims 5,6,7,8,9, see column 3, lines 21+ and column 5, lines 1-13 of Shifrin, et al.

Claims 10 and 11, see column 4, lines 63 of Shifrin et al.

Claim 12, see column 5, lines 1-13 of Shifrin et al.

Claim 14, see device of Shifrin et al.

Claims 15 and 16, see figures 1 and 5.

Claims 17,18, see bands 16 and 17 with fastening means 19 and 20.

Claims 19 and 20, see element 15 of Shifrin et al.

Claim 21 see elements 15-17 of Shifrin et al.

Claim 22 see fastening means 19 and 20.

Claim 23 see figures 1 and 5.

Claim 24, see figure 3.

Claims 27 and 28, see device of Shifrin et al.

Claim 29, as broadly worded, the device of Shifrin et al would inherently provide some degree of insulating properties.

**Claims 1, 9-11, 13, 25, 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Lombardi, et al (5824042).**

Lombardi, et al discloses a vascular implant including non-metallic fibers that is coated with silicone. The device is secured at a tissue site and provides means for the surgeon to locate the device in vivo. Applicant's arguments are directed to a surgical method for using a device, ie surgical marker. The physical characteristics of the marker includes an implant, biocompatible polymer for securing to an area of intervention wherein the implant is to enclose the area of intervention in a continuous circumferential manner. Please note the claims does not preclude the use of a device to enclose the interior dimension of the afflicted area.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1-4,9-12,14-24,27,28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shifrin et al (5476471) in view of Neizs et al (6652450).**

Shifrin et al discloses a device for correction of vascular junctions. Shifrin, et al fails to disclose the use of a visual marker as a means for providing the surgeon with the ability to align, identify and properly place the device at the intended site. Neizs et al teaches means for providing visual indicator to assist the surgeon to properly align, identify and place the device at the intended site. To provide the device of Shifrin, et al with identifying means similar to that as taught by Neizs, et al to aid the surgeon in properly placing the device at the intended site would have been obvious to one with ordinary skill in the art.

Claims 2 and 3, see column 15, lines 8+ of Neizs et al.

Claim 4, see column 3, lines 14+ of Shifrin et al.

Claims 5,6,7,8,9, see column 3, lines 21+ and column 5, lines 1-13 of Shifrin, et al.

Claims 10 and 11, see column 4, lines 63 of Shifrin et al.

Claim 12, see column 5, lines 1-13 of Shifrin et al.

Claim 14, see device of Shifrin et al.

Claims 15 and 16, see figures 1 and 5.

Claims 17,18, see bands 16 and 17 with fastening means 19 and 20.

Claims 19 and 20, see element 15 of Shifrin et al.

Claim 21 see elements 15-17 of Shifrin et al.

Claim 22 see fastening means 19 and 20.

Claim 23 see figures 1 and 5.

Claim 24, see figure 3.

Claims 27 and 28, see device of Shifrin et al.

Claim 29, as broadly worded, the device of Shifrin et al would inherently provide some degree of insulating properties.

**Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shifrin et al as applied to claim 12 above, and further in view of Fogarty et al (5800520).**

While Shifrin et al discloses the use of a memory alloy for reinforcing the polymer device, Fogarty et al teaches that memory plastics and alloys are interchangeable and equivalent in the medical prosthetic art. To substitute the polymer for the alloy to impart memory to the implant device would have been obvious to one with ordinary skill in the art based upon substitution of equivalent materials.

### **Response to Arguments**

Applicant's arguments filed 10/4/2004 have been fully considered but they are not persuasive.

Applicant's arguments concerning Shifrin et al has been considered and remains unpersuasive. Applicant's argues that the device of Shifrin is not intended to be placed on a transplant organ and the device is for correcting vascular junctions. Applicant's arguments are directed to a surgical method for using a device, ie surgical marker. The physical characteristics of the marker includes an implant, biocompatible polymer for securing to an area of intervention wherein the implant is to enclose the area of intervention in a continuous circumferential manner. The language directed to "**a marker intended to facilitate the location of a determined area of an internal organ transplant during secondary surgical procedures where an earlier surgical procedure has been performed, Whereby the internal organ can be native just as it can be a synthetic or autonomic implant and/or a combination of such organs, whereby the area of intervention can be the transition of an anastomosis, wherein the marker comprises a part designed as an implant for securing to the area of intervention during a primary operation to form a tactile barrier or boundary for the surgeon during the secondary operation between the area of intervention and the surrounding tissue**" sets forth the manner in which the device is to be employed. However, the manner by which the device is deployed, in this instance, fails to set forth further physical characteristics that distinguishes the device from that as disclosed by Shifrin.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **DAVID J ISABELLA** whose telephone number is 703-308-3060. The examiner can normally be reached on **MONDAY-FRIDAY**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **CORRINE MCDERMOTT** can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Primary Examiner  
Art Unit 3738

DJI  
MAY 28, 2004